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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,427	10/28/2003	Kurt-Reiner Geiss	7390-X03-020	4477

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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03/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/695,427

## Applicant(s)

GEISS ET AL.

## Examiner

Phyllis G. Spivack

## Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-32 is/are pending in the application.
- 4a) Of the above claim(s) 20,21,24-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 22, 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicants' Response filed December 7, 2007 to the Restriction Requirement mailed November 7, 2007 is acknowledged. Applicants have elected without traverse Group II, claims 19, 22 and 23.

On April 13, 2007 Applicants canceled claims 1-18 and presented new claims 19-25. A claim that was previously canceled may not be reinstated. Therefore, numbering of claims is not in accordance with 37 CFR 1.126. Original claims 1, 3-7 and 10 are renumbered consecutively beginning with the next number following the highest numbered claim previously presented, i.e., as claims 26-32.

Accordingly, claims 1, 3-7, 10 (now claims 26-32), 20 and 21 are withdrawn from consideration by the Examiner, as drawn to non-elected inventions, 37 CFR 1.142(b).

Applicants' Amendment filed August 2, 2007 and a Declaration under Rule 1.132 filed April 13, 2007 by Prof. Michael Weiss are further acknowledged and have been considered.

The subject matter presently under consideration are those methods of treating extreme physical stress in a human comprising administering at least 50 mg of L-threonine, claims 19, 22 and 23.

A complete list of all co-pending and related applications is requested when Applicants respond to this Office Action.

Objections and rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following rejections constitute those presently applied to the instant claims.

Claims 19, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

The recitations in claim 19 "including the raised serum prolactin levels are reduced and are increasingly coupled to the human central nervous system" and "including neurotransmitters, dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected" render the claims indefinite. It is unclear whether or not claim limitations are intended.

The recitation "extreme physical stress" is indefinite. The metes and bounds of "extreme" cannot be precisely determined.

The recitation "peripheral controls" is indefinite. Although it appears Applicants intend to include serum prolactin levels and neurotransmitters among peripheral controls, the metes and bounds of "peripheral controls" cannot be precisely determined.

Claims 19, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In the Reply filed August 2, 2007, Applicants provide a listing of support for the various limitations recited in instant claim 19. Said listing has been referenced to ascertain support.

The recitation "as evidenced by raised serum prolactin levels" lacks support in the specification as filed. In paragraph [0025] of the specification, measurement of the hypophyseen hormone prolactin is discussed, but no "**raised** serum prolactin level" is recited. The recitation represents new matter.

The recitation "resting the human" lacks support in the specification as filed. In paragraph [0027] of the specification, a recovery phase is noted, but no "**resting**" is recited. The recitation represents new matter.

The recitation "the peripheral controls" lacks support in the specification as filed. In paragraph [0035] of the specification, peripheral hormonal control and regulating system are discussed, but the recitation "peripheral controls" is claimed and is broader. The recitation represents new matter.

The recitation "...neurotransmitters dopamine, epinephrine, norepinephrine and serotonin, which are substantially unaffected,..." lacks support in the specification as filed. In paragraph [0025] of the specification, the recited hormones are discussed, but their being "substantially unaffected" is absent. The recitation represents new matter.

The subject matter noted *supra* is not properly described in the application as filed. See *In re Rasmussen*, 211 USPQ 323 (CCPA 1981).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 22 and 23 are rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, and, as

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containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 19 recites "treating extreme physical stress" and "to complete regeneration." There is insufficient written description for these claim limitations in the disclosure.

According to Stedman's Medical Dictionary, "stress" is *inter alia* any physical or psychological stimulus that can produce mental tension or physiological reactions that may lead to illness. Further, according to Stedman's Medical Dictionary, "regeneration" is any regrowth of lost or destroyed parts or organs.

Thus Applicants have used terms that are outside the generally recognized definitions that would reasonably be accepted by one skilled in the medical community. Although Applicants may be their own lexicographers, a description of the claimed invention with all of its limitations through words, structures, figures and/or diagrams that fully set forth the claimed invention, is required. Therefore, it is not clear Applicants were in possession of the full scope of the claimed methods at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614

February 25, 2008